IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ANITA KOHN, et al.,	:	
	:	
Plaintiffs,	:	**CIVIL ACTION**
	:	
v.	:	**NO. 19-40004**
	:	
ETHICON, INC., et al.,	:	
	:	
Defendants.	:	

MEMORANDUM

Tucker, J. **February 12, 2020**

This case arises from complications that Plaintiff, Anita Kohn, experienced following the surgical implantation of a Gynecare Gynemesh PS device and TVT-Obturator ("TVT-O") to treat her stress urinary incontinence ("SUI"), uterovaginal prolapse, and a rectocele. Pl. Mem. Opp'n Summ. J., 2, ECF No. 32. The medical devices were manufactured by Ethicon, a subsidiary of Johnson & Johnson (jointly, "Defendants"). Compl. ¶ 2–5, ECF No. 1. As a result of the damage Anita Kohn experienced from the complications, she and her husband, Ronald Kohn, (jointly, "Plaintiffs") sued Defendants. Notice of Removal, ECF No. 1. Plaintiffs originally asserted 18 counts against Defendants. *See* Am. Compl., ECF No. 12. Plaintiffs are now proceeding on only four claims including strict liability design defect, strict liability failure to warn, negligent design defect, and negligent failure to warn. Pl. Mem. Opp'n Summ. J., 3–4, ECF No. 32.

On October 16, 2018, Defendants moved for Summary Judgment. *See* Mot. Summ. J., ECF No. 28. The Court heard oral argument regarding the Motion for Summary Judgment on November 13, 2019. Upon consideration of Defendants' Motion for Summary Judgment, Plaintiffs' response thereto, and the oral arguments made by the Parties, **IT IS HEREBY**

ORDERED AND DECREED that Defendants' Motion for Summary Judgment is **GRANTED IN PART** and **DENIED IN PART**. Defendants' Motion for Summary Judgment is **GRANTED** for Plaintiffs' strict liability claims,[1] and those claims shall be **DISMISSSED WITH PREJUDICE**. Defendants' Motion for Summary Judgment is **DENIED** with respect to Plaintiffs' negligent design defect and failure to warn claims.[2]

I. FACTS AND PROCEDURAL HISTORY

Plaintiff, Anita Kohn, was diagnosed with stress urinary incontinence ("SUI"), uterovaginal prolapse, and a rectocele. Pl. Mem. Opp'n Summ. J., 2, ECF No. 32. To treat the ailment, Dr. Miles Murphy performed a surgery to implant a TVT-O and Gynemesh device in September 2009. Def. Mem. Supp. Summ. J., 2, ECF No. 29. Dr. Murphy performed the surgery at Abington Memorial Hospital in Abington, Pennsylvania. Def. Mem. Supp. Summ. J., 2. Shortly thereafter, Ms. Kohn developed complications from the procedure. Pl. Mem. Opp'n Summ. J., 2. On October 21, 2009, Dr. Murphy completed a revision surgery on Plaintiff, Anita Kohn. Pl. Mem. Opp'n Summ. J., 2. Even after the revision surgery, Plaintiffs claim that Ms. Kohn's condition continued to worsen. Ms. Kohn exhibited symptoms including dysuria, dyspareunia, and vaginal bleeding and pain. Pl. Mem. Opp'n Summ. J., 2. Despite the complications from the implantations, Dr. Murphy insists that the devices were implanted correctly. Pl. Mem. Opp'n Summ. J., 2.

Plaintiffs therefore filed suit against the Defendant device manufacturers, Ethicon and Johnson & Johnson, alleging 18 counts including: (1) negligence, (2) strict liability

[1] Counts 3 and 5 in the original Complaint. ECF No.1.

[2] Both the negligent design defect and negligent failure to warn claims are asserted in Count 1 of the original Complaint. Although the other 15 counts were not previously dismissed by the Court, Plaintiffs have chosen to no proceed on counts 2, 4, and 6–18 of the original Complaint. The Court, therefore, DISMISSES those claims.

manufacturing defect, (3) strict liability failure to warn, (4) strict liability defective product, (5) strict liability design defect, (6) common law fraud, (7) fraudulent concealment, (8) constructive fraud, (9) negligent misrepresentation, (10) negligent infliction of emotional distress, (11) breach of express warranty, (12) breach of implied warranty, (13) violation of consumer protection laws, (14) gross negligence, (15) unjust enrichment, (16) loss of consortium, (17) punitive damages, and (18) discovery rule and tolling. Compl. ¶¶ 111–277. Plaintiffs filed suit in the Philadelphia Court of Common Pleas on October 6, 2014, naming ten Defendants. Notice of Removal, ECF No. 1. Defendants filed an Answer on October 29, 2014. Answer, ECF No. 4.

This case was consolidated with other product liability cases regarding Ethicon's pelvic repair systems and transferred to the Southern District of West Virginia for pre-trial proceedings on November 18, 2014. Transfer Order, ECF No. 6. Plaintiffs then filed an Amended Short Form Complaint on March 24, 2015, naming only Ethicon and Johnson & Johnson as Defendants. Am. Compl., ECF No. 12. Plaintiffs continued to assert all 18 claims against Defendants. Am. Compl.

Upon completion of pre-trial proceedings, this case was remanded back to the Eastern District of Pennsylvania. *In Re Ethicon, Inc., Pelvic Repair System Products Liability Litigation*, MDL 2327; Conditional Remand Order, ECF No. 42. The District Court in West Virginia recommended that the cases be remanded to the jurisdiction from which they originally came "[f]or the convenience of the parties and in order to promote the final resolution of the cases." Ord. and Suggestion of Remand, ECF No. 36. Currently pending before the Court is Defendants' Motion for Summary Judgment, which was filed on October 16, 2018. Mot. Summ. J., ECF No. 28. Plaintiffs are proceeding with only four claims: strict liability design defect,

strict liability failure to warn, negligent design defect, and negligent failure to warn.[3] Pl. Mem. Opp'n Summ. J., 3–4. Upon consideration of Defendants' Motion, Plaintiffs' Response, and oral argument on November 13, 2019, Defendants' Motion for Summary Judgment is **GRANTED IN PART** and **DENIED IN PART**.

II. STANDARD OF REVIEW

A court should grant summary judgment only if the movant shows that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed R. Civ. P. 56(a). Factual disputes must be both *material* and *genuine* to defeat summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986) (emphasis added). Materiality depends on the applicable substantive law; a fact is material if it may affect the outcome of the lawsuit under the governing law. *Id*. at 247–248. A genuine dispute allows a reasonable jury to return a verdict for the nonmoving party. *Id*. at 248. When considering a motion for summary judgment the court must construe all evidence in the light most favorable to the nonmoving party. *Santini v. Fuentes*, 795 F.3d 410, 416 (3d Cir. 2015).

The Court finds that the Defendants are entitled to judgment as a matter of law on Plaintiffs' strict liability claims. However, the Court finds that genuine issues of material fact remain regarding Plaintiffs' negligence claims.

III. DISCUSSION

The Court will first discuss Plaintiffs' strict liability claims before analyzing the viability of Plaintiffs' negligence claims.

[3] Both the negligent design defect and negligent failure to warn are asserted by Plaintiff in Count I: Negligence of the original Complaint.

A. Defendants' Motion for Summary Judgment is Granted for Plaintiffs' Strict Liability Claims because Strict Liability Claims for Medical Devices Are Not Cognizable Under Pennsylvania Law.

Although the Pennsylvania Supreme Court has not squarely ruled on the topic, the Court believes that the current state of Pennsylvania law requires Plaintiffs' strict liability claims to be dismissed. In situations like this one, in which there is no controlling decision from the Pennsylvania Supreme Court, the Court must predict how the Pennsylvania Supreme Court would rule on the issue. *Berrier v. Simplicity Mfg., Inc.*, 563 F.3d 38, 45–46 (3d Cir. 2009). Plaintiffs bring two strict liability claims against Defendants—strict liability design defect and strict liability failure to warn. Because this Court predicts that the Pennsylvania Supreme Court would find that neither strict liability claim is cognizable under Pennsylvania state law, both are dismissed.

Plaintiffs strict liability claims allege that: (1) Defendants' products were unreasonably dangerous to patients and users (design defect); and (2) Defendants failed to properly warn and instruct the public, medical providers, and patients of the safest, most effective methods of use, and of the risks inherent to its pelvic mesh products (failure to warn). Compl. ¶¶ 123–130, 135–138, ECF No. 1. Plaintiffs further contend that the Defendants' design defect and failure to warn were proximate causes of the injuries that Plaintiffs sustained. Compl. ¶¶ 123–130, 135–138. Defendants, in response, argue that Pennsylvania state law does not recognize strict liability claims for medical devices. Def. Mem. Supp. Summ. J., 3, ECF No. 29.

Although the Pennsylvania Supreme Court has yet to definitively resolve this issue, some of its holdings are instructive. In *Hahn v. Richter*, the Pennsylvania Supreme Court affirmed a trial court's decision that plaintiffs cannot recover under strict liability failure to warn claims against prescription drug manufacturers. 673 A.2d 888, 889 (Pa. 1996). In reaching that conclusion, the

Pennsylvania Supreme Court relied on comment k of the Restatement (Second) of Torts § 402(A) which denies the application of strict liability to "unavoidably unsafe products" such as prescription drugs.[4] *See id.* Ten years later, the Pennsylvania Superior Court extended the reasoning articulated in *Hahn* to apply to medical devices. *Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. Ct. 2006) ("We find no reason why the same rational applicable to prescription drugs may not be applied to medical devices). In addition, the 2015 Pennsylvania Suggested Standard Civil Jury Instructions followed these rulings stating, "Pennsylvania courts have declined to apply strict liability in cases involving prescription drugs *and medical devices*, in accordance with comment k to the Restatement (Second) of Torts § 402(A)." Pa. Suggested Standard Civil Jury Instructions § 23.00 Subcommittee Note (May 2015) (emphasis added).

In response, Plaintiffs highlight that the Pennsylvania Supreme Court has not squarely ruled on whether strict liability claims can proceed against medical device manufacturers. Pl. Mem. Opp'n Summ. J., 5–9, ECF No. 32. In addition, Plaintiffs point to cases in which courts have

[4] Comment k, titled "Unavoidably Unsafe Products" reads: "There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk." Restatement Second, Torts § 402(A), comment k.

allowed strict liability claims to proceed against medical device manufacturers. Pl. Mem. Opp'n Summ. J., 5–9.

Specifically, Plaintiffs argue that *Beard v. Johnson & Johnson, Inc.* is instructive because the Pennsylvania Supreme Court allowed strict liability claims to proceed against the manufacturer of a surgical cutting and stapling instrument. 41 A.3d 823 (Pa. 2012); Pl. Mem. Opp'n Summ. J., 7. However, the Pennsylvania Supreme Court in *Beard* addressed the question of whether a "trial court's threshold risk-utility analysis should be limited to the particular one alleged to have caused the plaintiff harm." 41 A.3d 823, 824 (Pa. 2012). Notably, its ruling "recognize[d] the continuing state of disrepair in the arena of Pennsylvania strict-liability design defect law" and stated that "a majority consensus has not yet been attained in any case." *Id*. at 836. As a result, the Court here cannot read the Supreme Court's holding in *Beard* as a statement that Pennsylvania law allows strict liability claims to be asserted against medical device manufacturers going forward, as the Plaintiffs request. The Court cannot adopt that position considering the Pennsylvania Supreme Court's holding in *Hahn v. Richter*, which has yet to be overruled.

Plaintiffs also rely on the Pennsylvania Supreme Court's holdings in *Lance v. Wyeth* and *Tincher v. Omega Flex, Inc.* Pl. Mem. Opp'n Summ. J., 5–9. In *Lance*, the Pennsylvania Supreme Court rejected the application of comment k to plaintiff's claims that the drug was "effectively useless and dangerous." 85 A.3d 434, 451 (Pa. 2014). The court in *Lance* concluded that comment k does not "readily translate[] into the negligence arena, particularly given the very distinct treatment of strict-liability versus negligence theory" in Pennsylvania, and therefore allowed the plaintiff's claims to proceed on a theory of negligence. *Id*. at 451–52. The

Court does not find that *Lance* should be read to allow Plaintiffs' strict liability claims to proceed here, where the Court is faced with separate and distinct strict liability and negligence claims.

Plaintiffs also rely on *Tincher*, which allowed a plaintiff to pursue a strict liability claim by proving that the product was in a defective condition. 104 A.3d 328, 335 (Pa. 2014). However, *Tincher* dealt with steel tubing, not pharmaceutical products as the Court is faced with here. *Id*. at 336. Further, while the *Tincher* court discussed the question in dicta, it declined to create new precedential law on the matter. *See id.* Therefore, the Court finds that *Hahn* and *Creazzo* are the most analogous and instructive cases.

The Court acknowledges that this area of Pennsylvania law is unsettled. Some federal courts have predicted that the Pennsylvania Supreme Court would find that strict liability claims against medical device manufacturers are cognizable. *See e.g.*, *Schrecengost v. Coloplast Corp.*, No. 17-0220, 2019 WL 6465398, at *11–13 (W.D. Pa. Dec. 2, 2019); *see also Gross v. Coloplast Corp.*, No. 19-4385, 2020 WL 264691, at *3–4 (E.D. Pa. Jan. 17, 2020). However, those cases are just that—predictions—and federal courts, including this very Court, have also found that Pennsylvania law would not allow plaintiffs to bring strict liability claims in medical devices cases. *Esposito v. I-Flow Corp*., 2011 WL 5041374, at *4, n. 4 (E.D. Pa. Oct. 24, 2011) (holding that there can be no strict liability cause of action against the manufacturers of prescription drugs or pain pumps for failure to warn); *see Carson v. Atrium Med. Corp.*, 191 F. Supp. 3d 473, 476–77 (W.D. Pa. 2016); *Mills v. Ethicon*, 406 F. Supp. 3d 363, 379–80 (D.N.J. 2019) (agreeing with other federal courts in predicting that the Pennsylvania Supreme Court would extend comment k's application to strict liability design defect and failure to warn claims related to medical devices); *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 833 (E.D. Pa. 2016) ("We . . . conclude that comment k's prohibition of strict liability-failure to warn claims for prescription

drugs should also apply to medical devices."). As recently as June 2019, the Eastern District of Pennsylvania again predicted that the Supreme Court of Pennsylvania would rule that Pennsylvania law does not recognize strict liability claims for medical devices. *See Rosenberg v. Bard*, 387 F. Supp. 3d. 572, 575 (E.D. Pa. 2019) ("[D]oes Pennsylvania law recognize strict liability claim for a . . . prescription medical device? The Court predicts that the answer to this question is 'no.'").

As a result of the current state of Pennsylvania law, the Court finds that strict liability claims cannot proceed against medical device manufacturers. Defendants' Motion for Summary Judgement is therefore GRANTED for Plaintiff's strict liability claims.[5]

B. Defendants' Motion for Summary Judgment is Denied for Plaintiffs' Negligence Claims because Genuine Issues of Material Fact Remain.

Plaintiffs also wish to pursue negligence claims for failure to warn and design defect. To succeed on a claim of negligence under Pennsylvania law, a plaintiff must prove: (1) the defendant owed a duty to the Plaintiff; (2) defendant breached that duty; and (3) the breach was the proximate cause of the plaintiff's injuries. *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 776 (3d Cir. 2018).

In the Complaint, Plaintiffs claim that Defendants failed to exercise reasonable and ordinary care in the warning and marketing related to its Pelvic Mesh Products. Compl. ¶ 112. Specifically, Plaintiffs claim that Defendants failed to "use reasonable care in instructing and/or warning the public, health care providers, and patients, including Plaintiffs . . . of risks associated with the Products, so as to avoid unreasonable risk of harm to women in whom the Products were implanted." Compl. ¶ 113(f). In addition, Plaintiffs allege that Defendants failed "to

[5] Counts 3 and 5 in Plaintiffs' original Complaint.

design the Products so as to avoid an unreasonable risk of harm." Compl. ¶ 113(a). Plaintiffs claim that this negligence was the direct and proximate cause of Plaintiffs' injuries. Compl. ¶ 116.

In response, Defendants argue that Plaintiffs' negligence claims should fail as a matter of law because of the learned intermediary doctrine, which dictates that the manufacturer has an obligation to exercise reasonable care to inform the Plaintiff's prescribing physician about the risks of its product in the case of prescription medical devices. Def. Mem. Supp. Summ. J., 8. Defendants, therefore, argue that its duty was owed to physicians, not patients. Def. Mem. Supp. Summ. J., 8. Further, Defendants claim that Plaintiffs' negligence claims should fail because (1) the instructions for use ("IFU") warned of the adverse events that Plaintiff, Anita Kohn, suffered; (2) Defendants' failure to warn, if any, did not cause Plaintiffs' injuries because her physician was aware of the risk of the injuries; (3) Defendants' failure to warn, if any, was not the proximate cause of Anita Kohn's injuries because Plaintiff's physician did not rely on the warnings in the IFU; and (4) a warning would not have changed the outcome because Plaintiffs' physician continues to believe that he made the right decision to surgically implant the TVT-O and Gynemesh devices. Def. Mem. Supp. Summ. J., 9–11.

Defendants are correct that they had a duty to the prescribing physician to exercise reasonable care to inform them of facts which likely make the medical device dangerous. *In re Avandia Mktg., Sales Practices and Prods. Liab. Litig.*, 817 F. Supp 2d. 535, 545–46 (E.D. Pa. 2011). However, a product may be deemed defective if it lacks adequate warnings. *See e.g., Fletcher v. Raymond Corp.*, 623 A.2d 845, 848 (Pa. Super. Ct. 1993). For a warning to be adequate under Pennsylvania law, it must: (1) accurately and unambiguously convey the scope and nature of the risk, and (2) state the risk with sufficient specificity. *In re Avandia*, 817 F.

Supp 2d. at 546–47. To prevail on a failure to warn claim, Plaintiffs must also prove proximate causation by showing that the learned intermediary would have altered his behavior had the defendant issued a proper warning. *Demmler v. SmithKline Beecham Corp*., 671 A.2d 1151, 1155 (Pa. 1996).

Although Defendants claim that the warnings in the IFU were sufficient, during oral arguments Plaintiffs stated that "[t]he instructions for use in place at the time of Ms. Kohn's two implants did not mention the possibility of chronic dyspareunia, did not mention the possibility of chronic erosions . . . [Therefore,] Ethicon did not warn the physicians of those complications . . . [and] the physicians could not in turn warn[] patients." Transcript of Oral Argument at 11:9–21, *Kohn v. Ethicon*, Nov. 13, 2019 (No. 19-40004). Plaintiff's expert, Dr. John P. Brennan, also concluded that, "[t]he TVT-O mesh and Gynemesh . . . lacked adequate warnings to physicians about . . . risks." Pl. Mot. Opp'n Summ. J., Ex. B, ECF No. 31. Plaintiffs also point to the opinion of Dr. Bruce Rosenzweig who, in similar litigation against Ethicon, concluded that, "Ethicon's warnings and disclosures of adverse events in its TVT Instructions for Use . . . have been inadequate based on the adverse reactions and risks associated with the TVT." Pl. Mot. Opp'n Summ. J., Ex. C, 4. Therefore, the Court finds that there is a question of fact regarding the adequacy of Defendants' warning, which a jury must determine.

Further, the Court finds that there is a question of fact as to whether the alleged failure to warn was the proximate cause of Plaintiffs' injuries. Because there is a question as to whether Dr. Murphy was properly warned of the multitude of risks Plaintiffs claim are associated with Defendants' Pelvic Mesh devices, there is also a question of fact as to whether Dr. Murphy or Plaintiff, Anita Kohn, would have changed their course of care had they been properly warned of the associated risks. Dr. Murphy contends that, even as recently as 2018, he stands by his

decision to use the two products in Ms. Kohn's treatment. Def. Mot. Summ. J., Ex. D, Dr. Murphy Dep. 89:6–9, ECF No. 28. However, that statement does not directly address whether the warnings that he gave to Ms. Kohn would have differed had he been more properly informed of risks associated with Defendants' Pelvic Mesh medical devices. Such a warning may have affected Ms. Kohn's course of care.

Defendants also point out that Dr. Murphy did not "rely" on the IFUs for Ms. Kohn's surgery in arguing that Plaintiffs cannot establish proximate cause. Def. Mot. Summ. J., Ex. D, Dr. Murphy Dep. 71:10–72:17. Dr. Murphy did, however, mention that he "may have found some valuable information" in the IFU for the Gynemesh PS device. Def. Mot. Summ. J., Ex. D, Dr. Murphy Dep. 71:10–72:8. Therefore, there is a question of fact as to whether Dr. Murphy would have gained a different understanding of the risks associated with the devices had a proper warning of the risks associated with the device been included in the IFU. In addition, Plaintiffs point out that Dr. Murphy's credibility is in question given that he served as a preceptor for Ethicon. Transcript of Oral Argument at 9–10, *Kohn v. Ethicon*, Nov. 13, 2019 (No. 19-40004). Therefore, the Court finds that genuine issues of material fact remain to be assessed by a jury. As a result, Defendants' motion for summary judgement is DENIED as to Plaintiff's negligent design defect and failure to warn claims.

IV. CONCLUSION

For the foregoing reasons, Defendants' Motion for Summary Judgment is **GRANTED** with respect to Plaintiffs' strict liability claims and **DENIED** with respect to Plaintiffs' negligent design defect and failure to warn claims. An appropriate Order follows.